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Congress of the United States

House of Representatives

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March 9, 2007

Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 15-47
Rockville, MD 20857

Dear Dr. von Eschenbach:

In an interview with the Associated Press on March 6, you suggested that government regulation of tobacco, as proposed by current legislation, would be bad for the public health. As the sponsor of this legislation and a lifetime advocate for the public health, I am surprised and distressed by your comments. Your statements suggest a serious misunderstanding of the bill and appear to ignore overwhelming evidence that such regulation is necessary to address the continuing epidemic of tobacco-related death and disease. I am writing to correct the record and urge you to reconsider your position.

My first concern relates to your comments on the public health impact of reducing the level of nicotine in cigarettes. The proposed legislation would give the Food and Drug Administration (FDA) authority to identify, measure, and require changes in the amounts of tobacco product ingredients, including nicotine. It is incorrect, however, to suggest that FDA could require the reduction of nicotine in cigarettes without fully considering its impact on current smokers' behavior. In fact, the bill would empower FDA to make such decisions based on the best interests of the public health, taking into account the practical effect of any decision on the population as a whole.

This mandate to FDA — to establish standards for tobacco in the interest of the public health — is the core mechanism of the bill. It ensures that decisions will be based on science, not speculation, and protects against the conundrum of unintended consequences that you describe.

Your comments about tobacco product health claims also seem to reflect a misunderstanding of the legislation. The bill would not require FDA to deem any cigarette "safe." Instead, the bill would set an extremely high standard for approval of any tobacco product that claims, explicitly or implicitly, to pose a "modified risk" of death or disease. No such product would be allowed to reach consumers without sound

scientific evidence that it would significantly reduce the risk of harm to individual users and benefit the health of the public as a whole.

The bill also addresses the existing problem of unsupported health claims on tobacco products. In the absence of government regulation, tobacco producers are free to make claims about the "safety" of their products without any showing of scientific support. Such baseless claims are both common and effective in misleading the public about the hazards of tobacco. Your statements appear to overlook the current reality that children and adults rely on these claims to justify initiating or continuing use, with tragic results.

I am further dismayed at your suggestion that regulation of tobacco is inconsistent with FDA's mission. Under this legislation, FDA would oversee tobacco with the same objective that directs all its activities: to promote and protect the public health. The bill does not rely on FDA's traditional standards of approval because tobacco is not like any other product regulated by FDA. But the mission is the same, and no agency is better equipped to fulfill that mission.

Finally, I am alarmed by your statement that tobacco regulation is too "complex" for FDA to handle. As the chief guardian of our nation's food, drugs, vaccines, and medical devices, FDA tackles complex issues every day. Every aspect of your work demands both scientific expertise and careful consideration of risk and benefit. I fail to see why FDA could not apply its experience in both respects to the regulation of tobacco.

There is one point on which we agree: we now have an opportunity and an obligation to take "a comprehensive, public health approach" to the problem that is before us. This overdue legislation would accomplish just that. Further delay will not.

As you review the legislation, I urge you to correct your previous statements and to reconsider your position. In addition, I would welcome the opportunity to speak with you directly about this important matter. Given your lifelong dedication to public health and first-hand awareness of tobacco's toll as a cancer physician, I am eager to address your concerns. Please contact my office to arrange a time for us to speak.

Sincerely,

Henry A. Waxman
Chairman

cc: Tom Davis
Ranking Minority Member